

EXHIBIT 16

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| UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA | 1 I N D E X 2 EXHIBITS DESCRIPTION PAGE MARKED 3 Ex 226 Excel spreadsheet of data, 4 3MBH00049711-3 39 5 227 E-mail string, 3MBH00024866 95 6 228 E-mail string, 3MBH01054232-4 121 7 229 E-mail with attachment, 8 3MBH01621689-95 123 9 230 E-mail, 3MBH01486024 125 10 231 E-mail string, 3MBH01534469-71 131 11 232 E-mail string, 3M00585482-3 143 12 233 E-mail, 3MBH00518536 145 13 234 Sessler deposition transcript 14 dated November 20, 2015 150 15 235 Sessler deposition transcript 16 dated July 9, 2015 150 17 236 Sessler deposition transcript 18 dated May 27, 2015 150 19 20 21 22 23 24 25 |
| In Re: Bair Hugger Forced Air Warming Products Liability Litigation | |
| This Document Relates To: All Actions MDL No. 15-2666 (JNE/FLM) | |
| DEPOSITION OF DR. DANIEL SESSLER VOLUME I, PAGES 1 - 152 JANUARY 11, 2017 | |
| (The following is the deposition of DR. DANIEL SESSLER, taken pursuant to Notice of Taking Deposition, via videotape, at the Cleveland Clinic, P Building, Conference Room P77-013, 2070 East 90th Street, Cleveland, Ohio, commencing at approximately 10:11 o'clock a.m., January 11, 2017.) | |
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| 1 APPEARANCES: 2 On Behalf of the Plaintiffs: 3 Jan M. Conlin 4 CIRESI CONLIN L.L.P. 5 225 South 6th Street, Suite 4600 6 Minneapolis, Minnesota 55402 7 8 On Behalf of Defendants: 9 Corey L. Gordon and Peter J. Goss 10 BLACKWELL BURKE P.A. 11 432 South Seventh Street, Suite 2500 12 Minneapolis, Minnesota 55415 13 14 On Behalf of the Deponent: 15 Sandra M. DiFranco 16 Cleveland Clinic Law Department 17 2070 East 90th Street 18 Cleveland, Ohio 44195 19 20 21 22 23 24 25 | 1 P R O C E E D I N G S 2 (Witness sworn.) 3 DR. DANIEL SESSLER 4 called as a witness, being first duly sworn, 5 was examined and testified as follows: 6 ADVERSE EXAMINATION 7 BY MS. CONLIN: 8 Q. Good morning, Dr. Sessler. We've not met 9 before; correct? 10 A. Correct. 11 Q. Okay. I represent plaintiffs in an action 12 that's been brought against 3M involving the Bair 13 Hugger device. Do you understand that? 14 A. Yes. 15 Q. Okay. And you, in fact, were deposed a 16 number of times in connection with this Bair Hugger 17 device in connection with the Walton and Johnson Texas 18 litigations; correct? 19 A. I was deposed a number of times. I am not 20 sure what it was about. 21 Q. Okay. But you did -- 22 You were deposed three times as it relates 23 to your work and advice regarding the Bair Hugger 24 device; correct? 25 A. Correct. |

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| <p>1 from moving downstream from the filter into the hose 2 and into the blanket?</p> <p>3 MR. GORDON: Object to the form of the 4 question.</p> <p>5 A. Yes.</p> <p>6 Q. Okay. Have you ever seen anything where 3M 7 or Arizant have advised publicly that if a machine is 8 con -- found to be contaminated, that the filter 9 should be scrapped and treated as biohazardous waste?</p> <p>10 A. No.</p> <p>11 Q. Okay. Have you seen any documents or had 12 any discussions with 3M regarding advice they have 13 given to people who have called in, users of the Bair 14 Hugger, that you should not blow the dust out of the 15 machine?</p> <p>16 A. No.</p> <p>17 Q. Would that be something that you'd want to 18 know?</p> <p>19 A. That -- that sounds pretty technical.</p> <p>20 I'm -- I'm not sure how to interpret that.</p> <p>21 Q. Okay. If we look back at your study --</p> <p>22 Well let me ask it a different way. Let me 23 ask you another question on that. Do you know 24 whether, as these machines are used in surgery, after 25 surgery, whether the pathogens build up inside?</p> | <p>1 Q. Well you understand the two log reduction 2 line --</p> <p>3 I mean the DIN standard isn't designed to 4 evaluate Bair Hugger, right? What you were doing was 5 saying you can use the Bair Hugger and still meet the 6 DIN standard; right, doctor?</p> <p>7 A. The question was whether forced-air warming; 8 that is, warm air disturbs laminar flow and makes it 9 substantially less effective than it would be 10 otherwise, so the DIN standard is highly relevant. In 11 any case, whether or not you believe that, there's no 12 important difference here.</p> <p>13 Q. Okay. And if we look at Figure 2, you've 14 got -- the scale goes from 1, 10, 100 to 1000; right?</p> <p>15 A. It's a log scale.</p> <p>16 Q. And then 10,000; right?</p> <p>17 A. Yes.</p> <p>18 Q. All right.</p> <p>19 (Exhibit 226 was marked for 20 identification.)</p> <p>21 BY MS. CONLIN:</p> <p>22 Q. I've handed you, Dr. Sessler, what's been 23 marked as Exhibit 226, which is the raw data that Gary 24 Hansen produced regarding the study which is reflected 25 in (Belani) Exhibit 16, your paper.</p> |
| <p style="text-align: center;">Page 38</p> <p>1 A. No.</p> <p>2 Q. And you've just assumed that the filter is 3 going to do its job; right?</p> <p>4 A. Yes.</p> <p>5 Q. Why do you think the Bair Hugger had a HEPA 6 filter?</p> <p>7 A. Presumably, I was told that at some point, 8 but I don't remember how.</p> <p>9 Q. Okay. Now if we can look under the 10 "RESULTS" section of this study, which is on Bates 11 page 985630, under the "RESULTS" section you say, 12 "With the Arizant 522 upper body cover, background 13 par -- particle Cx were reduced to approximately 5 log 14 by the laminar flow system, and there were no 15 statistically significant or clinically important 16 differences among the 3 blower settings: off, ambient 17 air, and high." Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And how did you go about arriving at the 20 conclusion that there was no clinical -- clinically 21 important differences between the three settings?</p> <p>22 A. If you look at Figure 2, the columns for no 23 air, ambient air and warm air are virtually the same 24 height, and they're all way below the two log 25 reduction line.</p> | <p style="text-align: center;">Page 40</p> <p>1 MS. DIFRANCO: Have you a chance to look at 2 it?</p> <p>3 THE WITNESS: Yes.</p> <p>4 Q. Now this is the data that went into the 5 paper that you authored with Dr. Olmstead and Dr. 6 Kuehpmann; correct?</p> <p>7 A. I -- I assume.</p> <p>8 Q. Okay. And there were five runs both with 9 the 522 blanket and five runs with the 635 blanket; 10 right?</p> <p>11 A. Looks like it.</p> <p>12 Q. Okay. And if we take a look at the 635 13 blanket, which is on the right-hand side of Exhibit 14 226, --</p> <p>15 A. Yes.</p> <p>16 Q. -- the 625 is the underbody blanket; 17 correct, doctor?</p> <p>18 A. I'll take your word for it.</p> <p>19 Q. Okay. If you want to look back at the front 20 of your article, it indicates that it's the underbody 21 blanket, so --</p> <p>22 A. I'll take your word for it.</p> <p>23 Q. All right. So in the last run there were 28 24 particles measured over the -- the hypothetical 25 surgical site with the Bair Hugger off; correct?</p> |

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| <p>1 Q. And what did you understand that to be 2 reference to?</p> <p>3 A. Well, doing a bunch of t-tests comparing 4 different average results.</p> <p>5 Q. Well isn't he noting there, Mr. Hansen, that 6 if you use the t-test on the data that was generated 7 in connection with the Amersfoort and Utrecht testing, 8 that none of the differences are significant to within 9 a 95-percent confidence?</p> <p>10 A. That's what the note says, yes.</p> <p>11 Q. Okay. And then he writes, "It won't escape 12 notice that the number of samples is small;" correct?</p> <p>13 A. Yes.</p> <p>14 Q. Meaning that there were five runs for five 15 minutes each; correct?</p> <p>16 A. Correct.</p> <p>17 MR. GORDON: Object to the form.</p> <p>18 Q. Are you aware of surgeries that take place 19 over five minutes?</p> <p>20 A. That's completely irrelevant.</p> <p>21 Q. My question is: Are you aware of any 22 surgeries that take place over five minutes?</p> <p>23 A. Sure.</p> <p>24 Q. Okay. What?</p> <p>25 A. D&C.</p> | <p>1 reason why you'd need to use a Bair Hugger as opposed 2 to one of these resistive blankets; correct?</p> <p>3 A. Resistive blankets can cause burns. And 4 they haven't been used that much. How safe they are 5 in terms of thermal injury remains to be determined.</p> <p>6 Q. Okay. Setting aside thermal injury and 7 assuming you have a safe blanket, there would be no 8 medical reason to choose a Bair Hugger over a 9 resistive therapy; correct?</p> <p>10 MR. GORDON: Object to the form of the 11 question.</p> <p>12 A. Well if you stipulate that safety is the 13 same, the efficacy is comparable.</p> <p>14 Q. Okay. What if the safety of the Bair Hugger 15 was less because it increased the possibility that 16 bacterial pathogens could enter the surgical site?</p> <p>17 MR. GORDON: Object to the form of the 18 question.</p> <p>19 A. If -- if forced air causes harm, causes 20 complications, and you stipulate, based on nothing, 21 that some other tech -- technique doesn't, sure. 22 But -- but there's no basis for either of those 23 assumptions.</p> <p>24 Q. Okay. And in fact one of the things that 25 you're on record as saying is that the Bair Hugger has</p> |
| <p style="text-align: center;">Page 54</p> <p>1 Q. Okay. Anything else?</p> <p>2 A. Ear tubes.</p> <p>3 Q. I'd say that you're right on that one. I've 4 had -- my kids have had a few.</p> <p>5 You would agree with me that most surgeries 6 are not five minutes or less; correct?</p> <p>7 A. I agree.</p> <p>8 Q. And an orthopedic surgery might take an hour 9 as an example; correct?</p> <p>10 A. Correct.</p> <p>11 Q. Now you've actually also stated that the -- 12 whether forced-air warming is effective or necessary 13 in the first hour of a surgery is sort of an open 14 question; right?</p> <p>15 A. Depends how you define efficacy.</p> <p>16 Q. Okay. But you've in fact stated that 17 previously; correct?</p> <p>18 A. Depends how you define efficacy, but yes.</p> <p>19 Q. Okay. And you don't have any information to 20 suggest that a Bair Hugger in use for an orthopedic 21 surgery is somehow more effective than, say, a 22 resistive blanket; correct?</p> <p>23 A. We've tested two resistive blankets and they 24 had comparable efficacy.</p> <p>25 Q. Okay. There -- there would be no medical</p> | <p style="text-align: center;">Page 56</p> <p>1 been used in lots of surgeries with no evidence of 2 injury or infections; correct?</p> <p>3 A. As far as I know, forced air has not caused 4 thermal injury, used correctly.</p> <p>5 Q. Well I meant --</p> <p>6 My question was a little different.</p> <p>7 A. I'm sorry.</p> <p>8 Q. You're on record as stating you think 9 forced-air warming, Bair Hugger, is safe in surgeries 10 and doesn't increase the risk of infection; correct?</p> <p>11 A. I believe it reduces the risk of infection.</p> <p>12 Q. And in --</p> <p>13 A. Based -- based on available data, that's 14 what you have to conclude.</p> <p>15 Q. Okay. And in fact, one of the reasons you 16 say that is because you say it's been used in lots of 17 surgeries and there haven't been complaints; correct?</p> <p>18 A. No.</p> <p>19 Q. You haven't said that?</p> <p>20 A. That isn't the reason.</p> <p>21 Q. What isn't the reason, doctor?</p> <p>22 A. I -- I believe you said that I've said 23 that --</p> <p>24 Let -- let's go back to your question 25 because it was a two-part question and you -- you</p> |

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| <p>1 Q. Okay. Now in the next paragraph you say, 2 "What clinicians will want to see is basically 3 particle counts under three test circumstances (Off, 4 Ambient, and Warm)." Do you see that?</p> <p>5 A. Yup.</p> <p>6 Q. Then you write, "Any substantial increase 7 will still concern them and basically validate Scott's 8 point that forced-air warming increases risk. We can 9 try to convince them that the increase isn't important 10 or that operating rooms still meet DIN standards, but 11 that will be a bit tricky." Do you see that?</p> <p>12 A. Yup.</p> <p>13 Q. You knew that physicians would want to see 14 whether, in an individual case such as the 65 -- or 15 635 testing in Amersfoort, that there was a 16 substantial increase in particulates; correct?</p> <p>17 A. No, that's not what that means.</p> <p>18 Q. Okay. What -- what -- what were you saying 19 there?</p> <p>20 A. That first it --</p> <p>21 Note the third paragraph where I correct the 22 statistical approach. You need to look at all the 23 data; you can't just pick one piece of data, one line, 24 one run, and say this characterizes the results.</p> <p>25 Q. Okay.</p> | <p>1 best to consider the hospitals together since that 2 isn't really a factor of interest; and the cover type 3 could be unpaired." Do you see that?</p> <p>4 A. Uh-huh. Yes.</p> <p>5 Q. And in fact what you were describing there 6 is rather than show the results from the two hospitals 7 separately, you were going to group them together for 8 the purposes of the paper; right?</p> <p>9 A. Yes, because it -- that's the way it should 10 have been done. That's -- that's the correct way of 11 handling these data.</p> <p>12 Q. Why is it the correct way of handling these 13 data?</p> <p>14 A. Because the two hospitals together 15 characterize the general case better than either 16 hospital alone.</p> <p>17 Q. Well you know that ORs are different; right?</p> <p>18 A. Sure.</p> <p>19 Q. Okay. That can be a confounding factor; 20 right?</p> <p>21 A. Could be.</p> <p>22 MR. GORDON: Object to the form of the 23 question.</p> <p>24 Q. Could be a confounding factor. 25 Did you do any investigation as to whether</p> |
| <p style="text-align: center;">Page 62</p> <p>1 A. That's -- that's called data selection; it's 2 a type of research fraud.</p> <p>3 Q. Would you agree --</p> <p>4 A. You have to look at all the data.</p> <p>5 Q. Would you agree with me that any substantial 6 increase would concern clin -- clinicians?</p> <p>7 A. Average increase, not -- not results from 8 one run and one circumstance.</p> <p>9 Q. Would you agree with me that any substantial 10 increase would concern clinicians?</p> <p>11 MR. GORDON: Object to the form of the 12 question, also lack of foundation.</p> <p>13 A. Any substantial increase in average values 14 over all conditions would concern people.</p> <p>15 Q. Okay. And then you say in the third 16 paragraph, "Possibly the best statistical approach 17 would be an ANOVA with cover type...," correct?</p> <p>18 A. Yes.</p> <p>19 Q. And that's in fact what you guys have ended 20 up doing; correct?</p> <p>21 A. Correct.</p> <p>22 Q. Okay. And ANOVA is basically analysis of 23 variance; right?</p> <p>24 A. Yes.</p> <p>25 Q. And then you say, "But perhaps it would be</p> | <p style="text-align: center;">Page 64</p> <p>1 the machine that was used in Amersfoort might have 2 been a used one versus a new one?</p> <p>3 A. No.</p> <p>4 Q. Or that there was different protocols for 5 how they clean the OR?</p> <p>6 A. No. But it's not relevant to this study, 7 which used artificial particles. This had nothing to 8 do with bacteria.</p> <p>9 Q. Well I think we've already established you 10 don't know whether the Bair Hugger sucks in 11 particulates from off the floor and spews them out 12 into the surgical site; right?</p> <p>13 MR. GORDON: Object to the form of the 14 question.</p> <p>15 A. I don't think that's relevant to this study 16 where there are 20 million particles floating around 17 that are deliberately introduced.</p> <p>18 Q. So it wouldn't be of clinical interest to 19 you.</p> <p>20 A. You -- you're confusing two different 21 circumstances. One is whether forced-air warmers pick 22 up bacteria, retain bacteria or somehow eject 23 bacteria. If they do, that's a problem. A second 24 issue, which is what this paper is about, is whether 25 warm air interferes with the laminar flow column. Has</p> |

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| <p>1 nothing to do with bacteria.</p> <p>2 Q. Okay. And you -- you --</p> <p>3 I think we've established this. You're not</p> <p>4 an expert on laminar flow or how particulates move in</p> <p>5 the environment; right?</p> <p>6 A. I'm not.</p> <p>7 Q. So you -- you basic --</p> <p>8 Did you ask anybody why it was that the</p> <p>9 Amersfoort data appeared so different in terms of the</p> <p>10 particulate counts?</p> <p>11 MR. GORDON: Object to the form of the</p> <p>12 question.</p> <p>13 A. I don't remember.</p> <p>14 Q. Was it of interest to you?</p> <p>15 A. Absolutely.</p> <p>16 Q. What do you recall doing in connection with</p> <p>17 that data?</p> <p>18 A. When you do multicenter studies, it's</p> <p>19 absolutely routine and normal for the results to</p> <p>20 differ in the various centers. You -- you expect that</p> <p>21 just by random motion. And it's also true that the</p> <p>22 centers are truly different; they have different</p> <p>23 operating rooms, different anesthesia, different</p> <p>24 protocols, so you expect real differences among sites</p> <p>25 in a multicenter study. But you do a multicenter</p> | <p>1 A. Yes.</p> <p>2 Q. And then Dr. Olmstead took a crack at it; is</p> <p>3 that right?</p> <p>4 A. Yes.</p> <p>5 Q. And then you edited it; correct?</p> <p>6 A. "Edited" is a generous term. Virtually</p> <p>7 every word in the published manuscript was mine.</p> <p>8 Q. I've handed you, Dr. Sessler, what's been</p> <p>9 previously marked as Deposition Exhibit 79, which is a</p> <p>10 marked-up draft of your study which eventually was</p> <p>11 published and has been previously marked as (Belani)</p> <p>12 Exhibit 16; correct?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And you were part of this editing</p> <p>15 process; correct?</p> <p>16 A. Yes.</p> <p>17 Q. If we can take a look at draft -- the draft</p> <p>18 page seven, which bears Bates number 50592, and if we</p> <p>19 can look at the middle paragraph starting with "We</p> <p>20 found..."</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Midway down there there is a section</p> <p>23 which in this draft reads, "There were noticeable</p> <p>24 differences in the results between the two operating</p> <p>25 rooms, probably the result of small differences in</p> |
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| <p>1 study to enhance generalizability. You take all the</p> <p>2 results you have and you put them together and you</p> <p>3 present the average because that best characterizes</p> <p>4 what you know, and that's what we did here.</p> <p>5 Q. And in this case you did five samples, five</p> <p>6 runs five minutes each in two hospitals; correct?</p> <p>7 A. Yes.</p> <p>8 Q. And in fact you noted here that there were</p> <p>9 only five measurements; right?</p> <p>10 A. Correct.</p> <p>11 Q. So you're standing behind your proposition</p> <p>12 that this is not an under -- underpowered study;</p> <p>13 correct?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 A. Correct.</p> <p>17 Q. Could pooling the data from Amersfoort and</p> <p>18 Utrecht confound the data?</p> <p>19 A. No.</p> <p>20 Q. Why not?</p> <p>21 A. "Confounding" has a specific meaning, has to</p> <p>22 be something that's related to exposure and outcome.</p> <p>23 I don't see how pooling induces confounding.</p> <p>24 Q. Now I think we talked about this before, but</p> <p>25 Gary Hansen did the first draft; is that right?</p> | <p>1 draping around the OR table, and also perhaps due to</p> <p>2 differences in the laminar flow systems." Do you see</p> <p>3 that?</p> <p>4 A. I do.</p> <p>5 Q. And there was a deleted box beside that, and</p> <p>6 what was deleted is "The significantly higher counts</p> <p>7 seen with the blanket model 635 reflected conditions</p> <p>8 at OR Amersfoort" or "A..." Do you see that?</p> <p>9 A. I see it, yes.</p> <p>10 Q. Okay. Who made the decision to delete from</p> <p>11 this transcript that there had been significantly</p> <p>12 higher counts seen with the underbody blanket at the</p> <p>13 Amersfoort hospital?</p> <p>14 A. Well, whoever edited the document.</p> <p>15 Q. Do you know if that was Mr. Hansen at 3M?</p> <p>16 A. I have no idea who was editing at this</p> <p>17 point.</p> <p>18 Q. Okay. Was that something that you had</p> <p>19 drafted originally, that you had found significantly</p> <p>20 higher counts seen with the blanket model 635 in</p> <p>21 Amersfoort?</p> <p>22 A. I'm not sure I understand the question.</p> <p>23 Q. My question is: Do you know whether you</p> <p>24 were the person who originally put in the draft that</p> <p>25 there had been significantly higher counts seen with</p> |